



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

Date: December 11th, 2013

Subject: Efficacy Review for Steriplex SD Activator (Part B)
EPA Reg. No. 84545-10

From: Thao Pham
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Product Science Branch
Antimicrobials Division (7510P) *TP*

Thru: Mark Perry, Team Leader
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To: Karen Leavy, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: sBioMed, LLC
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Formulation from the Label:

(Part A)	<u>Active Ingredient(s)</u>	<u>% by wt.</u>
	Silver	00.015%
	<u>Inert Ingredients</u>	99.985%
	Total	100.000%

(Part B)	<u>Active Ingredient(s)</u>	<u>% by wt.</u>
	Hydrogen peroxide	22.000%
	Peroxyacetic acid	15.000%
	<u>Inert Ingredients</u>	63.000%
	Total	100.000%

I BACKGROUND

The product, Steriplex SD Activator (Part B) (EPA File Symbol 84545-10), is combined with Steriplex SD (Part A), prior to use. The activated product is an EPA-approved sporicide, one-step disinfectant (bactericide, fungicide, tuberculocide, virucide), non-food contact sanitizer, mildewstat, and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, food preparation, animal care, and hospital or medical environments. The label states that the product is effective in the presence of 5% serum contamination. The applicant submitted efficacy data for additional claims against Carbapenem Resistant *Klebsiella pneumoniae*, Carbapenem Resistant *Escherichia coli*. Efficacy data was also submitted to revise the contact time against Poliovirus type 1. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated June 18, 2013), three studies (MRID 49161101- 49161103), and the proposed label. A Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary were included in each study.

II USE DIRECTIONS

The activated product is designed for use on hard, non-porous surfaces, including: stainless steel including titanium-coated and medical grade stainless steel, chrome, plastic (vinyl, LD and HD polyethylene, and polypropylene), silicone rubber, metal, Formica, medical tubing, vinyl rubber, laminated surfaces, glass, acrylic plastic, Plexiglas, sealed fiberglass, glazed ceramic, glazed enamel, glazed porcelain, Corian, sealed granite, sealed limestone, sealed marble, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, and sealed finished woodwork. Directions on the proposed label provide the following information regarding preparation and use of the product:

As a one-step disinfectant: Pre-clean heavily soiled surfaces prior to application. Combine Steriplex SD (Part A) with Steriplex SD Activator (Part B) as instructed on the proposed label. Thoroughly apply the solution to surfaces using a spray, mop, cloth, sponge method, or by total immersion, covering the surface until wet. Allow the product to remain on the surface for 5 minutes. Allow surface to air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDY

1. MRID 491611-01 "AOAC Use-Dilution Method," Test organism: *Klebsiella pneumoniae* – Carbapenem Resistant (ATCC BAA-1705) for Steriplex SD Activator (Part B) (EPA Reg. No. 84545-10), by Gracia Schroeder. Study conducted at ATS Labs. Study completion date – June 10, 2013. Protocol Number: A15010.

This study was conducted against *Klebsiella pneumoniae* – Carbapenem Resistant (ATCC BAA-1705). Two lots (Lot Nos. Steriplex SD Part A 01-131151 + Steriplex SD Part B 502-1151 and Steriplex SD Part A 01-131152 + Steriplex SD Part B 502-1152) of the activated product, Steriplex SD, were tested using ATS Labs protocol # SBI01042213.UD.2 (copy provided). The test lots were prepared at the lower certified limit in accordance with the Certificate of Conformance. The product was activated by mixing the contents of Steriplex SD (Part A) with Steriplex SD Activator (Part B). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed for 15±2 minutes in a 48-54 hour old suspension of the test organism. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper after tapping each carrier against the side of the container to remove excess inoculum. The carriers were dried for 38 minutes at 35-37°C at 50% relative humidity. Each carrier was placed in 10 mL of the activated product for 5 minutes at 21.0°C. Immediately after placing each test carrier in the test tube, the tube was swirled approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth containing 0.1% sodium thiosulfate, 0.07% Lecithin, and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for one day prior to examination. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance.

Note: Antibiotic resistance of Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) and Carbapenemase detection on Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) were verified on a representative culture. A 10 µg Meropenem disk (an antibiotic of Carbapenem class) placed in the center of a Mueller Hinton agar plate inoculated with *Escherichia coli* (ATCC 25922) was streaked with prepared culture of a positive control (*Klebsiella pneumoniae* ATCC BAA-1705) and negative control (*Klebsiella pneumoniae* ATCC BAA-1706). The plate was incubated at 35-37°C for 16-24 hours and, following incubation, examined for the presence of the cloverleaf indentation. The examination confirmed production of carbapenemase then antibiotic resistance of Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) to Carbapenem (Meropenem). See page 18 of the laboratory report.

2. MRID 491611-02 "AOAC Use-Dilution Method," Test organism: *Escherichia coli* – Carbapenem Resistant (CDC 81371) for Steriplex SD Activator (Part B) (EPA Reg. No. 84545-11), by Gracia Schroeder. Study conducted at ATS Labs. Study completion date – June 10, 2013. Protocol Number: A15010.

This study was conducted against *Escherichia coli* – Carbapenem Resistant (CDC 81371). Two lots (Lot Nos. Steriplex SD Part A 01-131151 + Steriplex SD Part B 502-1151 and Steriplex SD Part A 01-131152 + Steriplex SD Part B 502-1152) of the activated product, Steriplex SD, were tested using ATS Labs protocol # SBI01042213.UD.1 (copy provided). The test lots were prepared at the lower certified limit in accordance with the Certificate of Conformance. The product was activated by mixing the contents of Steriplex SD (Part A) with Steriplex SD Activator (Part B). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed for 15±2 minutes in a 48-54 hour old suspension of the test organism. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper after tapping each carrier against the side of the container to remove excess inoculum. The carriers were dried for 38 minutes at 35-37°C at 52% relative humidity. Each carrier was placed in 10 mL of the activated

product for 5 minutes at 20.0°C. Immediately after placing each test carrier in the test tube, the tube was swirled approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth containing 0.1% sodium thiosulfate, 0.07% Lecithin, and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for one day prior to examination. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance.

Note: Antibiotic resistance of Carbapenem Resistant *Escherichia coli* (CDC 81371) and Carbapenemase detection on Carbapenem Resistant *Escherichia coli* (CDC 81371) were verified on a representative culture. A 10 µg Meropenem disk (an antibiotic of Carbapenem class) placed in the center of a Mueller Hinton agar plate inoculated with *Escherichia coli* (ATCC 25922) was streaked with prepared culture of a positive control (*Klebsiella pneumoniae* ATCC BAA-1705) and negative control (*Klebsiella pneumoniae* ATCC BAA-1706). The plate was incubated at 35-37°C for 16-24 hours and, following incubation, examined for the presence of the cloverleaf indentation. The examination confirmed production of carbapenemase then antibiotic resistance of Carbapenem Resistant *Escherichia coli* (CDC 81371) to Carbapenem (Meropenem). See page 18 of the laboratory report.

3. MRID 491611-03 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test organism: Poliovirus type 1 (ATCC VR-1562) CHAT strain for Steriplex SD Activator (Part B) (EPA Reg. No. 84545-11), by Gracia Schroeder. Study conducted at ATS Labs. Study completion date – March 7, 2013. Protocol Number: A14696.

This study was conducted against Poliovirus type 1 CHAT Strain (ATCC VR-1562) in the presence of 5% fetal bovine serum for a 5-minute contact time. Registrant has requested that this study not be reviewed for efficacy.

V RESULTS

MRID Number	Organism	Contact Time	Test Substance	No. Exhibiting Growth/Total No. Tested	Dried Carrier Count (CFU/ carrier)
491611-01	<i>Klebsiella pneumoniae</i> (Carbapenem Resistant) ATCC BAA-1705	5 minutes	Steriplex SD Part A 01-131151 Steriplex SD Part B 502-1151	0/10	3.3×10^6
			Steriplex SD Part A 01-131152 Steriplex SD Part B 502-1152	0/10	
491611-02	<i>Escherichia coli</i> (Carbapenem Resistant) CDC 81371	5 minutes	Steriplex SD Part A 01-131151 Steriplex SD Part B 502-1151	0/10	1.0×10^6
			Steriplex SD Part A 01-131152 Steriplex SD Part B 502-1152	0/10	

VI CONCLUSIONS

1. The submitted efficacy data support the use of the activated product, Steriplex SD, as a one-step disinfectant with bactericidal activity against Carbapenem Resistant *Klebsiella pneumoniae* on hard, non-porous surfaces with a 5-minute contact time. Both replications indicated a passing result with no carriers demonstrating growth. .
2. The submitted efficacy data support the use of the activated product, Steriplex SD, as a one-step disinfectant with bactericidal activity against Carbapenem Resistant *Escherichia coli* on hard, non-porous surfaces with a 5-minute contact time. Both replications indicated a passing result with no carriers demonstrating growth.
3. The submitted efficacy data was not reviewed for the use of the activated product, Steriplex SD, as a one-step disinfectant with virucidal activity against Poliovirus type 1 on hard, non-porous surfaces with a 5-minute contact time.

VII LABEL

1. The proposed label claims that the activated product, Steriplex SD, is an effective disinfectant against Carbapenem Resistant *Escherichia coli* and Carbapenem Resistant *Klebsiella pneumoniae*, on hard, non-porous, non-food contact surfaces for a 5-minute contact time. Data provided **support** this claim.
2. The applicant must make the following revisions to the proposed label for the product, Steriplex SD Part A:
 - On page 2 of the proposed label, change "Enterobacteriaceae" to read "Enterobacteriaceae."
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 - On pages 2, 5, 6, and 11 of the proposed label, change "Carbapenem Resistant" to read "Carbapenem Resistant."
 - On pages 2, 5, 6, and 11 of the proposed label, change "*Klebsiella pneumonia*" to read "*Klebsiella pneumoniae*."
 - On page 5 of the proposed label, change "*Exherichia coli*" to read "*Escherichia coli*."
 - **Add ATCC numbers** for all microorganisms identified on the proposed label.